



Mail

Troublesome inconsistencies in the federal regulation of pyrethrin-based shampoos

To the editor,

Sheldon Wagner's report¹ of fatal asthma in a child after use of a pyrethrin-based animal shampoo touches on several matters that bear further clarification. Under current federal regulatory practices, the Environmental Protection Agency (EPA) regulates various pyrethrin-containing products used to control insect infestations on animals as well as other pyrethrin-containing products applied to inanimate objects (eg, furniture and carpets) for the same purpose. Shampoos intended for use by humans, however, may have even higher concentrations of pyrethrins than the product involved in the reported fatality and are regulated by the Food and Drug Administration (FDA). The ways in which these products are regulated by the 2 agencies differ significantly.

EPA regulations specifically prohibit any claim of safety on the product label,² and federal law limits the nature of claims made for a pesticide "as a part of its distribution or sale."³ On the other hand, the FDA's final regulatory review of over-the-counter (OTC) pediculicide products includes a specific finding that they are "safe," even though the products must bear precautionary labeling.⁴ Thus, while manufacturers of products intended for use on animals and inanimate objects cannot describe them as "safe" or "nontoxic," manufacturers of OTC shampoos intended for use on humans have claimed that they may be labeled as "safe," citing the FDA document.

Using provisions of New York's General Business Law, which prohibit deceptive advertising, the New York State Attorney General's office has succeeded in eliminating false and misleading safety claims from the advertising of well over 100 pesticide manufacturers and pest control services in the state of New York. However, the dilemma created by

inconsistent EPA and FDA regulatory practices is apparent in 2 cases we prosecuted recently. While each respondent agreed to cease and desist from any safety claims for EPA-regulated sprays intended for use on pets and inanimate objects, they asserted a right to make such claims on their OTC shampoos for human use. They did, however, agree to accompany any such shampoo advertising claims with disclaimers that the label contained important health-related precautions.⁵ Because of jurisdictional limits, the advertising restrictions we obtained are only enforceable in the state of New York, so it is possible that OTC shampoos sold in other states carry safety claims without the disclaimers required in New York.

Although the FDA allows label claims of safety provided the specified precautions and other information are listed, acute allergic reactions to pyrethrin insecticides may occur from the use of any of these products, including those intended for use on humans. Physicians should know that these reactions may occur and that labels that inform the choices of their patients are subject to inconsistent regulations. Physicians should warn patients about the potential consequences of the use of these products and be alert to the full spectrum of potential sources and types of exposure.

Michael H Surgan

Environmental Protection Bureau
New York State Attorney General's Office
120 Broadway
New York, NY 10271
michael.surgan@oag.state.ny.us

References

- 1 Wagner, S. Fatal asthma in a child after use of an animal shampoo containing pyrethrin [letter]. *West J Med* 2000;173:86-87.
- 2 Labeling Requirements for Pesticides and Devices. 40 CFR §156 (1996).
- 3 Federal Insecticide, Fungicide and Rodenticide Act, 7 USC §136.
- 4 Pediculicide drug products for over-the-counter human use; final monograph. 58 *Federal Register* 65452 (1993) (codified at 21 CFR §358).
- 5 Assurances of Discontinuance in the Matter of Pfizer Inc, Respondent (in re: RID products) and in the Matter of Hogil Pharmaceutical Corp (in re: A-200 products).